

§ 25.60

available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[62 FR 40592, July 29, 1997, as amended at 68 FR 24879, May 9, 2003]

Subpart F—Other Requirements

§ 25.60 Environmental effects abroad of major agency actions.

(a) In accordance with Executive Order 12114, “Environmental Effects Abroad of Major Federal Actions” of January 4, 1979 (44 FR 1957, January 9, 1979), the responsible agency official, in analyzing actions under his or her program, shall consider the environmental effects abroad, including whether the actions involve:

(1) Potential environmental effects on the global commons and areas outside the jurisdiction of any nation, e.g., oceans and the upper atmosphere.

(2) Potential environmental effects on a foreign nation not participating with or otherwise involved in an FDA activity.

(3) The export of products (or emissions) that in the United States are prohibited or strictly regulated because their effects on the environment create a serious public health risk.

(4) Potential environmental effects on natural and ecological resources of global importance designated under the Executive Order.

(b) Before deciding on any action falling into the categories specified in paragraph (a) of this section, the responsible agency official shall determine, in accordance with section 2-3 of the Executive Order, whether such actions may have a significant environmental effect abroad.

(c) If the responsible agency official determines that an action may have a significant environmental effect abroad, the responsible agency official shall determine, in accordance with section 2-4 (a) and (b) of the Executive Order, whether the subject action calls for:

(1) An EIS;

(2) A bilateral or multilateral environmental study; or

(3) A concise environmental review.

21 CFR Ch. I (4-1-05 Edition)

(d) In preparing environmental documents under this subpart, the responsible official shall:

(1) Determine, as provided in section 2-5 of the Executive Order, whether proposed actions are subject to the exemptions, exclusions, and modification in contents, timing, and availability of documents.

(2) Coordinate all communications with foreign governments concerning environmental agreements and other arrangements in implementing the Executive Order.

PART 26—MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE REPORTS, MEDICAL DEVICE QUALITY SYSTEM AUDIT REPORTS, AND CERTAIN MEDICAL DEVICE PRODUCT EVALUATION REPORTS: UNITED STATES AND THE EUROPEAN COMMUNITY

Sec.

26.0 General.

Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices

26.1 Definitions.

26.2 Purpose.

26.3 Scope.

26.4 Product coverage.

26.5 Length of transition period.

26.6 Equivalence assessment.

26.7 Participation in the equivalence assessment and determination.

26.8 Other transition activities.

26.9 Equivalence determination.

26.10 Regulatory authorities not listed as currently equivalent.

26.11 Start of operational period.

26.12 Nature of recognition of inspection reports.

26.13 Transmission of postapproval inspection reports.

26.14 Transmission of preapproval inspection reports.

26.15 Monitoring continued equivalence.

26.16 Suspension.

26.17 Role and composition of the Joint Sectoral Committee.

26.18 Regulatory collaboration.

26.19 Information relating to quality aspects.

26.20 Alert system.

26.21 Safeguard clause.

Food and Drug Administration, HHS

§ 26.0

APPENDIX A TO SUBPART A—LIST OF APPLICABLE LAWS, REGULATIONS, AND ADMINISTRATIVE PROVISIONS.

APPENDIX B TO SUBPART A—LIST OF AUTHORITIES.

APPENDIX C TO SUBPART A—INDICATIVE LIST OF PRODUCTS COVERED BY SUBPART A.

APPENDIX D TO SUBPART A—CRITERIA FOR ASSESSING EQUIVALENCE FOR POST- AND PREAPPROVAL.

APPENDIX E TO SUBPART A—ELEMENTS TO BE CONSIDERED IN DEVELOPING A TWO-WAY ALERT SYSTEM.

Subpart B—Specific Sector Provisions for Medical Devices

- 26.31 Purpose.
- 26.32 Scope.
- 26.33 Product coverage.
- 26.34 Regulatory authorities.
- 26.35 Length and purpose of transition period.
- 26.36 Listing of CAB's.
- 26.37 Confidence building activities.
- 26.38 Other transition period activities.
- 26.39 Equivalence assessment.
- 26.40 Start of the operational period.
- 26.41 Exchange and endorsement of quality system evaluation reports.
- 26.42 Exchange and endorsement of product evaluation reports.
- 26.43 Transmission of quality system evaluation reports.
- 26.44 Transmission of product evaluation reports.
- 26.45 Monitoring continued equivalence.
- 26.46 Listing of additional CAB's.
- 26.47 Role and composition of the Joint Sectoral Committee.
- 26.48 Harmonization.
- 26.49 Regulatory cooperation.
- 26.50 Alert system and exchange of postmarket vigilance reports.

APPENDIX A TO SUBPART B—RELEVANT LEGISLATION, REGULATIONS, AND PROCEDURES.

APPENDIX B TO SUBPART B—SCOPE OF PRODUCT COVERAGE.

APPENDICES C–F TO SUBPART B [RESERVED]

Subpart C—“Framework” Provisions

- 26.60 Definitions.
- 26.61 Purpose of this part.
- 26.62 General obligations.
- 26.63 General coverage of this part.
- 26.64 Transitional arrangements.
- 26.65 Designating authorities.
- 26.66 Designation and listing procedures.
- 26.67 Suspension of listed conformity assessment bodies.
- 26.68 Withdrawal of listed conformity assessment bodies.
- 26.69 Monitoring of conformity assessment bodies.
- 26.70 Conformity assessment bodies.
- 26.71 Exchange of information.

26.72 Sectoral contact points.

26.73 Joint Committee.

26.74 Preservation of regulatory authority.

26.75 Suspension of recognition obligations.

26.76 Confidentiality.

26.77 Fees.

26.78 Agreements with other countries.

26.79 Territorial application.

26.80 Entry into force, amendment, and termination.

26.81 Final provisions.

AUTHORITY: 5 U.S.C. 552; 15 U.S.C. 1453, 1454, 1455; 18 U.S.C. 1905; 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 393; 42 U.S.C. 216, 241, 242i, 262, 264, 265.

SOURCE: 63 FR 60141, Nov. 6, 1998, unless otherwise noted.

§ 26.0 General.

This part substantially reflects relevant provisions of the framework agreement and its sectoral annexes on pharmaceutical good manufacturing practices (GMP's) and medical devices of the “Agreement on Mutual Recognition Between the United States of America and the European Community” (the MRA), signed at London May 18, 1998. For codification purposes, certain provisions of the MRA have been modified for use in this part. This modification is done for purposes of clarity only and shall not affect the text of the MRA concluded between the United States and the European Community (EC), or the rights and obligations of the United States or the EC under that agreement. Whereas the parties to the MRA are the United States and EC, this part is relevant only to the Food and Drug Administration's (FDA's) implementation of the MRA, including the sectoral annexes reflected in subparts A and B of this part. This part does not govern implementation of the MRA by the EC, which will implement the MRA in accordance with its internal procedures, nor does this part address implementation of the MRA by other concerned U.S. Federal agencies. For purposes of this part, the terms “party” or “parties,” where relevant to FDA's implementation of the MRA, should be considered as referring to FDA only. If the parties to the MRA subsequently amend or terminate the MRA, FDA will modify this part accordingly,

§ 26.1

21 CFR Ch. I (4–1–05 Edition)

using appropriate administrative procedures.

Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices

§ 26.1 Definitions.

(a) *Enforcement* means action taken by an authority to protect the public from products of suspect quality, safety, and effectiveness or to assure that products are manufactured in compliance with appropriate laws, regulations, standards, and commitments made as part of the approval to market a product.

(b) *Equivalence* of the regulatory systems means that the systems are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. Equivalence does not require that the respective regulatory systems have identical procedures.

(c) *Good Manufacturing Practices* (GMP's). [The United States has clarified its interpretation that under the MRA, paragraph (c)(1) of this section has to be understood as the U.S. definition and paragraph (c)(2) as the EC definition.]

(1) GMP's mean the requirements found in the legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

(2) GMP's are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this subpart, GMP's include, therefore, the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorization/product authorization or license holder or applicant and ensures the product is

made in compliance with its specifications (qualified person certification in the EC).

(d) *Inspection* means an onsite evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP's and/or commitments made as part of the approval to market a product.

(e) *Inspection report* means the written observations and GMP's compliance assessment completed by an authority listed in Appendix B of this subpart.

(f) *Regulatory system* means the body of legal requirements for GMP's, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

[63 FR 60141, Nov. 6, 1998; 64 FR 16348, Apr. 5, 1999]

§ 26.2 Purpose.

The provisions of this subpart govern the exchange between the parties and normal endorsement by the receiving regulatory authority of official good manufacturing practices (GMP's) inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems of the parties, which is the cornerstone of this subpart.

§ 26.3 Scope.

(a) The provisions of this subpart shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community (EC) before products are marketed (hereafter referred to as "preapproval inspections") as well as during their marketing (hereafter referred to as "postapproval inspections").

(b) Appendix A of this subpart names the laws, regulations, and administrative provisions governing these inspections and the good manufacturing practices (GMP's) requirements.

(c) Appendix B of this subpart lists the authorities participating in activities under this subpart.

(d) Sections 26.65, 26.66, 26.67, 26.68, 26.69, and 26.70 of subpart C of this part do not apply to this subpart.